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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/455,543	12/07/1999	STEVEN M. BESSETTE	45112-045	5289

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EXAMINER	
PATTEN, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/455,543	BESSETTE ET AL.	
	Examin r	Art Unit	
	Patricia A Patten	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2003 and 15 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-14 and 16* is/are pending in the application.

4a) Of the above claim(s) *7-14 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1, 5-14 and 16 are pending in the application.

Election/Restrictions

Applicant's election without traverse of the species of eugenol and forskolin in the response of 8/18/03 is acknowledged. Because claims 7-16 are drawn to non-elected species, these claims have been withdrawn from consideration on the merits.

Claims 1 and 5-6 were examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, claim 6 recites 'wherein eugenol is selected on a basis of therapeutic treatment for soft tissue cancer'. It is noted that Applicant has not pointed out in the Specification where support for this new limitation occurs. After reviewing the Specification, this language was not found by the Examiner. As is discussed in the rejection under 35 USC 112 Second paragraph, this phrase is confusing, and the Examiner does not clearly understand what this phrase means and cannot therefore verifiably conclude that this concept was actually conceptualized in the original Specification. Applicant is asked to delete the New Matter from the claim in order to overcome this rejection or point out to the Examiner the exact location of this phrase or idea in the Specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As indicated *supra*, claim 6 recites 'wherein eugenol is selected on a basis of therapeutic treatment for soft tissue cancer'. It is first noted that this statement does not materially change the composition claims. However, it is not perfectly clear what Applicant intends for this statement to mean. Does Applicant intend for this to mean that the eugenol is in some amount which is effective or that eugenol is a part of the composition because it had already been known in the art to treat soft tissue cancer? Clarification is necessary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 5-6 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Agarwal et al. (US 4,751,224) in view of Saeed et al. (1995-Abstract). Claims 1 and 5-6 are drawn to a composition for treating cancer wherein said composition comprises eugenol and forskolin. Claims are further drawn to wherein the soft tissue cancer is breast cancer, and wherein the eugenol is selected on a basis of therapeutic treatment for soft tissue cancer.

Agarwal et al. (US 4,751,224) disclosed a method for treating metastasizing cancers with forskolin (Abstract). Agarwal et al. explained that:

> "While in the blood stream or shortly after adhesion to endothelium, intravascular cancer cells become surrounded by thrombotic material consisting of platelets, erythrocytes and fibrin. Thrombus formation appears to be a significant event in the establishment of tumor colonies in the capillary beds of various organs. Blood platelets also appear to play an important role in tumor metastasis; it has been demonstrated that many metastasizing tumor cell lines induce platelet aggregation both in vitro and in vivo. Furthermore, upon aggregation, platelets release a substance or substances which promote tumor growth" (co.1, lines 30-41).

Agarwal et al. clearly taught that forskolin blocked platelet aggregation via stimulation of adenylate cyclase and therefore increasing the cellular AMP concentration (col. 2 line 54- col.3, line 23) and showed blocking of platelet aggregation with forskolin in a mouse lung melanoma (soft tissue) model (Example 1, col.4).

Saeed et al. (1995-Abstract) disclosed that Eugenol strongly inhibited PAF-induced platelet aggregation with an inhibition of thromboxane-A2 and 12-hydroxy-eicosatetraenoic acid in human platelets (CAPLUS Abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art to inhibit platelet formation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

One of ordinary skill in the art would have had a reasonable expectation that since both of the ingredients were known in the art to inhibit platelet aggregation, that the combination would have provided for an additive effect. Due to the explanation that was given by Agarwal et al. pertaining to the clear link between thrombosis (platelet aggregation) and tumor metastasis, the ordinary artisan would have had a reasonable expectation that eugenol, a known anti-platelet aggregating compound, would have had *at least some* effect on metastasizing soft-tissue tumors such as lung tumors even though the art did not specifically state such.

Again, with regard to the terminology which recites 'wherein eugenol is selected on a basis of therapeutic treatment for soft tissue cancer' does not materially change the composition. Eugenol is eugenol, independent of the practitioner's reason for incorporation into the composition. This reasoning is absent any indication that the act of choosing eugenol because of an intrinsic

characteristic of the eugenol would materially change eugenol (please see rejection under 35 USC 112 Second paragraph *supra*).

Accordingly, the instant claims, where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments pertain solely to the previous rejections which have been removed and are thereby moot in light of the new rejections *supra*.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (703) 308-1189. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Patricia A Patten
Examiner
Art Unit 1654

10/31/03

PATRICIA PATTEN
PATENT EXAMINER